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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276-1243.

Project: Substance Abuse Prevention and Treatment Block Grant Synar Report Format, FFY 2017-2019--(OMB No. 0930-0222) -- Revision

Section 1926 of the Public Health Service Act [42 U.S.C. 300x-26] stipulates that funding Substance Abuse Prevention and Treatment Block Grant (SABG) agreements for alcohol and drug abuse programs for fiscal year 1994 and subsequent fiscal years require states to have in effect a law providing that it is unlawful for any manufacturer, retailer, or distributor of tobacco products to sell or distribute any such product to any individual under the age of 18. This section further requires that states conduct annual, random, unannounced inspections to ensure compliance with the law; that the state submit annually a report describing the results of the inspections, the activities carried out by the state to enforce the required law, the success the state has achieved in reducing the availability of tobacco products to individuals under the age of 18,

and the strategies to be utilized by the state for enforcing such law during the fiscal year for which the grant is sought.

Before making an award to a State under the SABG, the Secretary must make a determination that the state has maintained compliance with these requirements. If a determination is made that the state is not in compliance, penalties shall be applied. Penalties ranged from 10 percent of the Block Grant in applicable year 1 (FFY 1997 SABG Applications) to 40 percent in applicable year 4 (FFY 2000 SABG Applications) and subsequent years. Respondents include the 50 states, the District of Columbia, the Commonwealth of Puerto Rico, the U.S. Virgin Islands, Guam, American Samoa, the Commonwealth of the Northern Mariana Islands, Palau, Micronesia, and the Marshall Islands.

Regulations that implement this legislation are at 45 CFR 96.130, are approved by OMB under control number 0930-0163, and require that each state submit an annual Synar report to the Secretary describing their progress in complying with section 1926 of the PHS Act. The Synar report, due December 31 following the fiscal year for which the state is reporting, describes the results of the inspections and the activities carried out by the state to enforce the required law; the success the state has achieved in reducing the availability of tobacco products to individuals under the age of 18; and the strategies to be utilized by the state for enforcing such law during the fiscal year for which the grant is sought. SAMHSA's Center for Substance Abuse Prevention will request OMB approval of revisions to the current report format associated with Section 1926 (42 U.S.C. 300x-26). The report format is not changing significantly. Any changes in either formatting or content are being made to simplify the reporting process for the states and to clarify the information as the states report it; both outcomes will facilitate consistent, credible, and

efficient monitoring of Synar compliance across the states. All of the information required in the new report format is already being collected by the states. Specific changes are listed below:

Clarification Changes

To decrease the need for supplemental questions and reporting, additional instruction has been included in 3 portions of the report.

In Section I (Compliance Progress), the following clarification changes are being made with respect to the Annual Synar Report:

Question 1b: Changes to state law – This question asks about changes in state laws that impact the state’s protocol for conducting Synar inspections and has been edited to include an option for changes to state law concerning changes in the definition of tobacco products. Many states are changing the definition of tobacco products in their state laws to include electronic nicotine delivery systems, which would impact the types of products that could be included in Synar surveys.

Question 1c: Changes to state law – This question asks about changes to state youth access to tobacco laws and has been edited to include an option for changes to state law concerning additional product categories to their youth tobacco access law. While some states have changed the definition in the state law to include electronic nicotine delivery systems, smokeless tobacco, and other tobacco products, other states have added these products as additional product categories in addition to tobacco products.

Question 2: Describe how the Annual Synar Report and the state plan were made public prior to submission of the ASR. This question asks states to describe how they make their ASR public prior to submission. States have been asked to provide a web address and the date the ASR was posted to that web address if they choose to post the ASR on an agency website. The ASR format has been clarified to provide a separate text box to enter both of these pieces of information. The time frame was corrected per the comments.

Questions 4d-f – Coordination with Agency that Receives the FDA State Enforcement Contract – These close-ended questions ask the state to list the agency that is under contract to the FDA to enforce federal youth access laws, to describe the relationship between the state's Synar program and this agency, and to identify if the state uses data from the FDA enforcement inspections for the Synar survey. This question has been edited to include skip logic and response options if a state does not have a current contract with the FDA.

Questions 5b, 5c, 5d, 5e, 5f: Enforcement Agencies, Evidence of Enforcement and Frequency of Enforcement – These questions have been clarified so it is clear that they refer to enforcement of state youth access laws, and not federal or local youth access laws. In addition, these questions have been re-ordered (but the wording has not been changed) to improve logical flow of the questions. In addition, question 5e has been edited to include separate response options to allow states to describe each of the additional activities listed in the question stem to encourage states to describe each of those activities fully. The timeframe for this question was corrected per the

comments.

Questions 8a and 8b: Sampling Frame Coverage Study – Language was changed in these questions to emphasize the word sampling regarding the frame coverage study as requested during the comment period.

In Section II (Intended Use), the following clarification change is being made:

Question 3 – State Challenges: This question asks states to identify and describe their challenges in implementing the Synar program. This question has been edited to include separate response options to allow states to describe each of the challenges listed in the question stem to encourage states to describe each of the challenges fully and to make targeted technical assistance requests.

In Appendix C (Synar Survey Inspection Protocol Summary), the following changes are being made:

Title: The title of this Appendix has been edited to reflect that it is the summary of the state's inspection protocol and that the Appendix itself is not detailed enough to serve as the entirety of the state's inspection protocol.

Questions 4– Type of Tobacco Products – These questions, which ask the state to define the type of tobacco products requested during Synar inspections and to describe the protocol for tobacco type selection, have been edited to separate the options of including small cigars and cigarillos

and to add the option of including electronic nicotine delivery systems or electronic cigarettes.

Questions 5a and b— The previous question 5 has been separated into two sections to ensure states are able to fully describe the methods used to recruit, select and train adult supervisors for the survey separately from the methods used to recruit, select, and train youth inspectors.

Content Changes

The content of the Synar Report has changed little. The content changes that have been made address the need to 1) clarify the intent of information requested via the addition of clarifying questions, and 2) reduce the need for State Project Officers to ask additional questions to supplement the originally submitted Report. These additions and changes are essential to SAMHSA's ability to adequately assess state and jurisdictional compliance with the Synar regulation.

In Section I (Compliance Progress), the following changes are being made with respect to the Annual Synar Report:

Question 6: Changes to the sampling methodology – This question asks states if their sampling methodology has changed from the previous year. If there has been a change, a sub-question has been added to document how that change was communicated to SAMHSA. Since this change requires prior approval, a state that had not received prior approval will have the opportunity to discuss the process used to determine the need for a change. Language in the report format and the instructions was adjusted to reflect the comments. The time period was also corrected per the

comments.

Question 9: Changes to the inspection protocol – This question asks states if its inspection protocol has changed from the previous year. If there has been a change, a sub-question has been added to document how that change was communicated to SAMHSA. Since this change requires prior approval, a state that had not received prior approval will have the opportunity to discuss the process used to determine the need for a change. Existing questions 9a, 9b, and 9c have been renumbered to account for this new sub-question. Language in the report format and the instructions was adjusted to reflect the comments.

In Appendix B (Synar Survey Sampling Methodology), the following changes are being made:

Question 4 – Vending machine inclusion in Synar Survey – This question, whether asks vending machines are included in the Synar survey and the reasons for their elimination if they are not included. Because many states have a contract with the FDA and are actively enforcing the vending machine requirements of the Family Smoking Prevention and Tobacco Control Act, some states that include vending machines in their sampling protocols do not sample any because there are few eligible vending machines remaining on their list frame. A second part has been added to this question to determine how vending machines are sampled.

There are no changes to Forms 1-5 or Appendix D.

Annual Reporting Burden

45 CFR Citation	Number of respondents \\1\\	Responses per respondents	Total number of responses	Hours per response	Total hour burden
Annual Report (Section 1-- States and Territories) 96.130(e)(1-3)	59	1	59	15	885
State Plan (Section II--States and Territories) 96.130(e)(4,5)96.130(g)	59	1	59	3	177
Total	59				1,062

\\1\\ Red Lake Indian Tribe is not subject to tobacco requirements.

Written comments and recommendations concerning the proposed information collection should be sent by **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]** to the SAMHSA Desk Officer at the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB). To ensure timely receipt of comments, and to avoid potential delays in OMB's receipt and processing of mail sent through the U.S. Postal Service, commenters are encouraged to submit their comments to OMB via e-mail to: OIRA_Submission@omb.eop.gov. Although commenters are encouraged to send their comments via e-mail, commenters may also fax their comments to: 202-395-7285. Commenters may also mail them to: Office of Management and Budget, Office of Information and Regulatory Affairs, New Executive Office Building, Room 10102, Washington, D.C. 20503.

Summer King,
Statistician.

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